UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,449	08/16/2006	Mariko Kuroda	P29911	8465

7055 7590 01/14/2008

GREENBLUM & BERNSTEIN, P.L.C.
1950 ROLAND CLARKE PLACE
RESTON, VA 20191

EXAMINER	
ANDERSON, DENISE R	

ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
01/14/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No.	Applicant(s)	
	10/579,449	KURODA ET AL.	
	Examiner	Art Unit	
	Denise R. Anderson	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/16/2006 and 5/10/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. Applicant's letter, dated September 12, 2006, did not contain Form PTO-1449. Per the letter, the examiner did consider the following:

   a. The English language translation of the Written Opinion (Form PCT/ISA/237).

   b. Form PCT/ISA/338.

   c. Form PCT/ISA/373.

   d. International Application No. PCT/JP2004/017082.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4 and 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al. (WO/2002/087735, Jul. 11, 2002 – the original was in Japanese, so the English version, US 2004/0167237 A1, will be cited). Kim et al. is analogous art since the Kim et al. membrane is "usable in blood dialysis, plasma separation, etc." Kim et al., Abstract, lines 1-6. Kim et al. further teaches a hollow fiber membrane spun from a solution of aromatic polysulfone, polyvinyl pyrrolidone, and N-methyl-2-pyrrolidone – and the measured zeta potential of the hollow fiber was -1 at pH 7.4, using a 0.001 mol/l

potassium chloride solution. Kim et al., Comparative Example 1 at ¶ 195 and in Table 1; ¶ 159. Independent claim 1 appears below in italics with the prior art and examiner's comments in normal font. The patentability analysis follows for dependant claims 2-4 and 6-7.

Claim 1. A hollow fiber membrane (Kim et al., ¶ 195, line 17-18) *for blood purification* (Kim et al., Abstract, lines 1-6) *having a integrally continuous structure* (Kim et al., ¶ 195, the hollow fiber membrane was spun from a "homogeneous spinning solution" indicating an integrally continuous structure) *from the inner membrane surface to the outer membrane surface, the membrane comprising a hydrophobic polymer* (Kim et al., ¶ 195, lines 1-5, the hollow fiber membrane was spun from "aromatic polysulfone" which is a hydrophobic polymer) *and a hydrophilic polymer* (Kim et al., ¶ 195, lines 1-5, the hollow fiber membrane was spun from "polyvinyl pyrrolidone" which is a hydrophilic polymer), *and exhibiting a zeta potential* (Kim et al., Comparative Example 1 at ¶ 195 and in Table 1 where the measured zeta potential was -1 at a pH of 7.4; ¶ 158 where the zeta potential measurement was described and included using a 0.001 mole/l potassium chloride solution) *on the inner surface thereof of greater than -3.0 mV but less than 0 mV at pH 7.5, when measured using a sample with an embedded resin on the outer side for allowing the electrolyte solution to flow through only the inside of the hollow fiber, and using a 0.001 mol/l potassium chloride aqueous solution as an electrolyte solution.*

In summary, Kim et al. anticipates claim 1.

4. Kim et al. anticipates claim 1 and further teaches a hollow fiber made from a polysulfone-based resin (claim 3) and a polyvinyl pyrrolidone (claim 4). (Kim et al., ¶ 195, lines 1-5, where the hollow fiber membrane was spun from "aromatic polysulfone" and "polyvinyl pyrrolidone." Kim et al. also teaches a dense layer thickness of 1 to 20 μm and this includes applicant's recited range of 1 to 5 μm in claim 7. In summary, Kim et al. anticipates claims 3-4 and 7.

5. With regards to the hollow fiber membrane properties recited in claims 2 and 6, Kim et al., in Table 1, further teaches an albumin sieving coefficient of 0.011 (1.1% versus the recited < 0.6%) and a protein adsorption amount of 4.2 mg/m^2 (versus the recited < 65 mg/m^2). Kim et al. also teaches that a "first object of the present invention" is to provide a hollow fiber membrane "that can separate a human serum albumin with a molecular weight of about 67,000 from proteins with a molecular weight in the range of 30,000-40,000." Kim et al., ¶ 19, lines 7-13; ¶ 6, lines 4-13. Thus, the Kim et al. hollow fiber membranes will remove more than 45% of a polyvinyl pyrrolidone with a weight average molecular weight of 40,000.

6. Kim fails to disclose the property limitations recited in claim 2, subparagraphs (d) and (e), or the property limitations recited in claims 6. However, a membrane's properties are determined by its composition, and the polymer membrane of the reference has the same composition as the polymer membrane described by instant claims 1, 3 and 4. For these reasons, the cited properties are presumed to be inherent to the membrane of the reference. See MPEP 2112. In summary, Kim et al. anticipates claims 2 and 6.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (WO/2002/087735, Jul. 11, 2002 – the original was in Japanese, so the English version, US 2004/0167237 A1, will be cited) as applied to 4 above, and further in view of Kozawa et al. (US Patent No. 6,355,730 B1, Mar. 12, 2002). Kozawa et al. is analogous art in that it discloses hollow fiber membranes formed from polysulfone-based resins and polyvinyl pyrrolidone for use in dialysis. Kozawa et al., Abstract, lines 1-8; Column 2, lines 48-52.

11. Kim et al. discloses the claimed invention except for a polyvinyl pyrrolidone membrane content of 3.0% to 5.0%. Kozawa et al. teaches that the hollow fiber membranes have a polyvinyl pyrrolidine content "in an amount of 3 to 15% by weight of the polysulfone," which encompasses the 3.0% to 5.0 wt. % range recited in claim 5. Kozawa et al., Column 13, lines 63-66. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the Kim et al. membrane to have a 3.0% to 5.0% pyrrolidone membrane content, as taught by Kozawa et al., since Kozawa et al. states in the Abstract that such a modification would produce a membrane material "useful in dialysis." Therefore, Kim et al., in view of Kozawa et al., discloses or suggests all claim 5 limitations.

12. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (WO/2002/087735, Jul. 11, 2002 – the original was in Japanese, so the English version, US 2004/0167237 A1, will be cited) as applied to claim 1 above, and further in view of Carlsen et al. (US Patent No. Re. 36,914, Oct. 17, 2000). Carlsen et

al. is analogous art in that a "dialysate filter" (applicant's blood purification apparatus) is disclosed that has "an asymmetric microporous, hollow fiber membrane." Carlsen et al., Title, Figures 1 and 2.

13. With regards to claim 8, Carlsen et al., in Figure 2, discloses a cylindrical container with two nozzles (labeled "inlet port" and "outlet port") for flow dialysate. Carlsen et al. further teaches a potting material to separate the hollow inside of the membrane from the outside of the membrane. Carlsen et al., Column 11, lines 30-32. Finally, in Figure 2, Carlsen et al. discloses a header cap at both ends of the apparatus. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have installed the Kim et al. hollow fiber membranes into a blood purification apparatus, as taught by Carlsen et al., since Kim et al. states in the Abstract, lines 1-5 that the Kim et al. hollow fiber membranes are "usable in blood dialysis" and Carlsen et al states in the Title that the Carlsen et al. apparatus is a "dialysate filter" incorporating "hollow fiber membranes." In summary, Kim et al., in view of Carlsen et al., discloses or suggests all claim 8 limitations.

14. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (WO/2002/087735, Jul. 11, 2002 – the original was in Japanese, so the English version, US 2004/0167237 A1, will be cited), in view of Carlsen et al. (US Patent No. Re. 36,914, Oct. 17, 2000), as applied to claim 8 above. Kim et al., in view of Carlsen et al., discloses the claimed invention except for explicitly stating that the phosphorus clearance is 180 ml/min for a 1.5 m^2 membrane area. Because the structure of the Kim et al. hollow fiber membrane is the same as that recited by applicant and structure

governs phosphorous clearance, the Kim et al. hollow fiber membrane in the Carlsen apparatus would exhibit the phosphorous clearance of 180 ml/min for a 1.5 m^2 membrane area. Thus, Kim et al., in view of Carlsen et al., discloses or suggests all claim 9 limitations.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The references are in the art of blood purification and contain several limitations of the hollow fiber membrane recited in the claims.

US 6802971 B2	10/12/2004	Gorsuch; Reynolds et al.	210/500.23
US 6432309 B1	08/13/2002	Fuke; Masaya et al.	210/500.41
WO 0178805A1	10/25/2001	Gorsuch et al.	A16M 1/16
US 6103117 A	08/15/2000	Shimagaki; Masaaki et al.	210/321.71
US 5938929 A	08/17/1999	Shimagaki; Masaaki et al.	210/645
US 5762798 A	06/09/1998	Wenthold; Randal M. et al.	210/500.23
US 5683584 A	11/04/1997	Wenthold; Randal M. et al.	210/500.23
US 5474680 A	12/12/1995	Eguchi; Tamiyuki	210/500.23

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Denise R. Anderson whose telephone number is 571-270-3166. The examiner can normally be reached on Monday through Thursday, from 8:00 am to 6:00 pm.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter D. Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DRA

DAVID SAMPLE
SUPERVISORY PATENT EXAMINER